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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/009,663 | 02/08/2002 | Colin Dunlop | GRIHAC P38AUS | 8376 |

20210 7590 10/21/2003
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,663

Applicant(s)

DUNLOP, COLIN

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47 - 92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47 - 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 11/13/01 and 8/20/02 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information disclosure statements have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Specification

1. The disclosure is objected to because of the following informalities: There are no headings throughout the specification. On page 10, lines 4, 19 and 30; page 12, line 22; page 15, line 9; and page 16, line 4 the “microprocessor” is referred to with reference numeral 9. Previously in the disclosure the “microprocessor” is referenced with numeral 2 and an “input” is referenced with numeral 9. On page 10, lines 18 and 31 and page 11, line 1 the “transducer” is referred to with reference numeral 13. Previously in the disclosure the “transducer” is referenced with numeral 13b and a “membrane” is referenced with numeral 13. The British variation “analyse” and its derivatives are used throughout the specification and claims.

Appropriate correction is required.

Drawings

2. The drawings are objected to because “FIG. 3b” is not shown on the drawing of the front view of the device. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 90 – 92 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,969,459 to Gusakov.

In reference to claims 90 – 92, Gusakov discloses device for monitoring a patient under medical care having a control means arranged to receive input from a temperature sensor sensing the body temperature of a patient, to provide an alarm if the temperature goes above or below a predetermined threshold, and a controls a heating device (Col. 2, line 43 – Col. 3, line 10).

5. Claims 47, 48, 50, 57, 59, 60, 62, 63, 65, 68 - 70, 72, 74, 83 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,410,297 to Joseph et al.

In reference to claims 47, 48, 50, 57, 59, 60, 62, 63, 65, 68 – 70, 72, 74, 83 and 85, Joseph et al. discloses a method and device for monitoring a human animal patient under medical care including a sensor arrangement to detect motion of the patient (Col. 5, lines 39 – 45), a control means (48) to process signals received from the sensor arrangement to determine if the motion is indicative of patient arousal, and to provide an alarm (Col. 8, lines 35 – 37) should the detected motion be beyond a predetermined threshold indicative of patient arousal (Col. 8, lines 23 – 34). The sensor arrangement includes a pad on which the patient lies (Col. 3, lines 3 – 7). Joseph et al.

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discloses assessing a baseline motion rate and setting the threshold above the baseline level (Col. 4, lines 2 – 11). An input means is provided that enables the predetermined level to be set (Col. 8, lines 48 – 54).

6. Claims 47, 48, 50 – 52, 57, 59, 62, 63, 66, 67, 72 – 74, 76, 77, 80, 83 and 85 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,751,214 to Cowley et al.

In reference to claims 47, 48, 50 – 52, 57, 59, 62, 63, 66, 67, 72 – 74, 76, 77, 80, 83 and 85, Cowley et al. discloses a method and device for monitoring a human animal patient under medical care including a sensor arrangement to detect motion of the patient, a control means (66) to process signals received from the sensor arrangement (Col. 3, lines 61 – 65) to determine if the motion is indicative of patient arousal, and to provide an alarm should the detected motion be beyond a predetermined threshold indicative of patient arousal (Col. 3, lines 58 - 65). Cowley et al. discloses the alarm being provided if the motion of the patient falls below a predetermined level or ceases to be detected (Col. 4, lines 37 – 41; Col. 4, line 63 – Col. 5, line 7). The control means and display (Col. 3, line 45) as disclosed by Cowley et al. is mounted in a housing that is capable of being mounted on a cage or a plurality of cages if desired (Figure 6). Cowley et al. discloses monitoring the bodily motion of the patient by way of the sensor arrangement, and analyzing the motion to determine the medical condition of the patient (Col. 3, lines 58 – 54).

7. Claims 47, 48, 50, 51, 57, 59, 62, 63, 65, 66, 72, 74, 77, 78, 80, 82 – 85 and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,780,798 to Hall-Jackson.

8. In reference to claims 47, 48, 50, 51, 57, 59, 62, 63, 65, 66, 72, 74, 77, 78, 80, 82 – 85 and 87, Hall- Jackson discloses a method and device for monitoring a human animal patient under medical care including a sensor arrangement to detect motion of the patient, a control means (26) to process signals received from the sensor arrangement to determine if the motion is indicative of patient

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arousal, and to provide an alarm (Col. 4, lines 15 – 19) should the detected motion be beyond a predetermined threshold indicative of patient arousal (Abstract, lines 6 – 9). The alarm is triggered if motion of the patient has ceased. The sensor arrangement includes a pad on which the patient lies (Col. 3, lines 62 – 66). Hall-Jackson discloses monitoring the bodily motion of the patient by way of the sensor arrangement, and analyzing the motion by tracking and graphing the rate of motion over a period of time to determine the medical condition of the patient (Col. 4, lines 54 – 57). Hall-Jackson discloses determining whether or not a patient is displaying signs of painfulness (Col. 4, lines 54 – 57).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 47 – 50, 57 – 64, 69 – 70, 72, 74, 75, 77 – 81, 83 – 86, 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0702978 to Medtronic, Inc. in view of U.S. Patent No. 5,410,297 to Joseph et al.

In reference to claims 47 – 50, 57 – 64, 69 – 70, 72, 74, 75, 77 – 81, 83 – 86, 88 and 89, Medtronic, Inc. discloses a method and device for monitoring a human animal patient under medical care including a sensor arrangement to detect bodily motion of the patient, a control means to process signals received from the sensor arrangement to determine if the motion is indicative of patient arousal (Col. 4, lines 24 – 33; Col. 5, lines 42 – 46). Medtronic, Inc. discloses assessing a baseline motion rate that corresponds to the motion rate of the patient at the time the baseline

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assessment is made, and setting a threshold at a rate above the baseline level (Col. 5, lines 2 – 8). A separate respiratory motion arrangement measures respiratory motion of the patient, and a comparing a signal from the respiratory motion sensor to an activity sensor, to obtain an indication of bodily motion of the patient (Col. 16, line 52 – Col. 17, line 28). The controls means automatically provides default settings for the predetermined level. Medtronic, Inc. discloses monitoring the bodily and respiratory motion of the patient by way of the sensor arrangement, and analyzing the motion by tracking and graphing the rate of motion over a period of time and applying trend analysis to determine the medical condition of the patient (Col. 16, line 52 – Col. 17, line 28). Medtronic, Inc. discloses controlling a peripheral device depending upon the motion of the patient (Col. 3, lines 56 – 58). The device as disclosed by Medtronic, Inc. is capable of being used to monitor a patient recovering from anesthesia. Medtronic, Inc. discloses the sensor arrangement being responsive to bodily motion, and performing a function in response to the bodily motion increasing beyond a predetermined threshold (Col. 5, lines 32 – 46). However, Medtronic, Inc. fails to disclose the sensor being a pad on which the patient lies, or providing an alarm when the bodily motion goes beyond the predetermined threshold. Joseph et al. teaches an activity sensor that is a pad on which the patient lies (Col. 3, lines 4 – 7), and an alarm that is triggered in response to bodily motion increasing beyond a predetermined threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the activity sensor as disclosed by Medtronic, Inc. with the pad sensor as taught by Joseph et al. in order to continuously monitor the patient's movement unobtrusively and without the need to attach a sensor to the patient. Furthermore, it would have been obvious to modify the device as disclosed by Medtronic, Inc. to include an alarm as taught by Joseph et al. in order to alert a caregiver that a patient is arousing so

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that discomfort to the patient associated with electrical stimulation while the patient is awake can be avoided in the event that manual shut off of the stimulation is needed.

11. Claims 53 – 56 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0702978 to Medtronic, Inc. in view of U.S. Patent No. 5,410,297 to Joseph et al. as applied to the claims above, and further in view of U.S. Patent No. 4,969,459 to Gusakov.

Gusakov discloses monitoring a patient under medical care having a control means arranged to receive input from a temperature sensor proximate a patient sensing the body temperature of a patient and to provide an alarm if the temperature goes above or below a predetermined threshold (Col. 2, line 43 – Col. 3, line 10). It would have been obvious to one having ordinary skill in the art to modify the device as disclosed by Medtronic, Inc. to include the capabilities of temperature monitoring and alarm notification as taught by Gusakov in order to alert a caregiver that a patient's body temperature is no longer in a normal range.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,498,652 to Varshneya et al. and UK Patent Application No. 2,227,322.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

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JMLF

October 15, 2003


MAX F. HINDENBURG
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